Postmarket Monitoring by FDA
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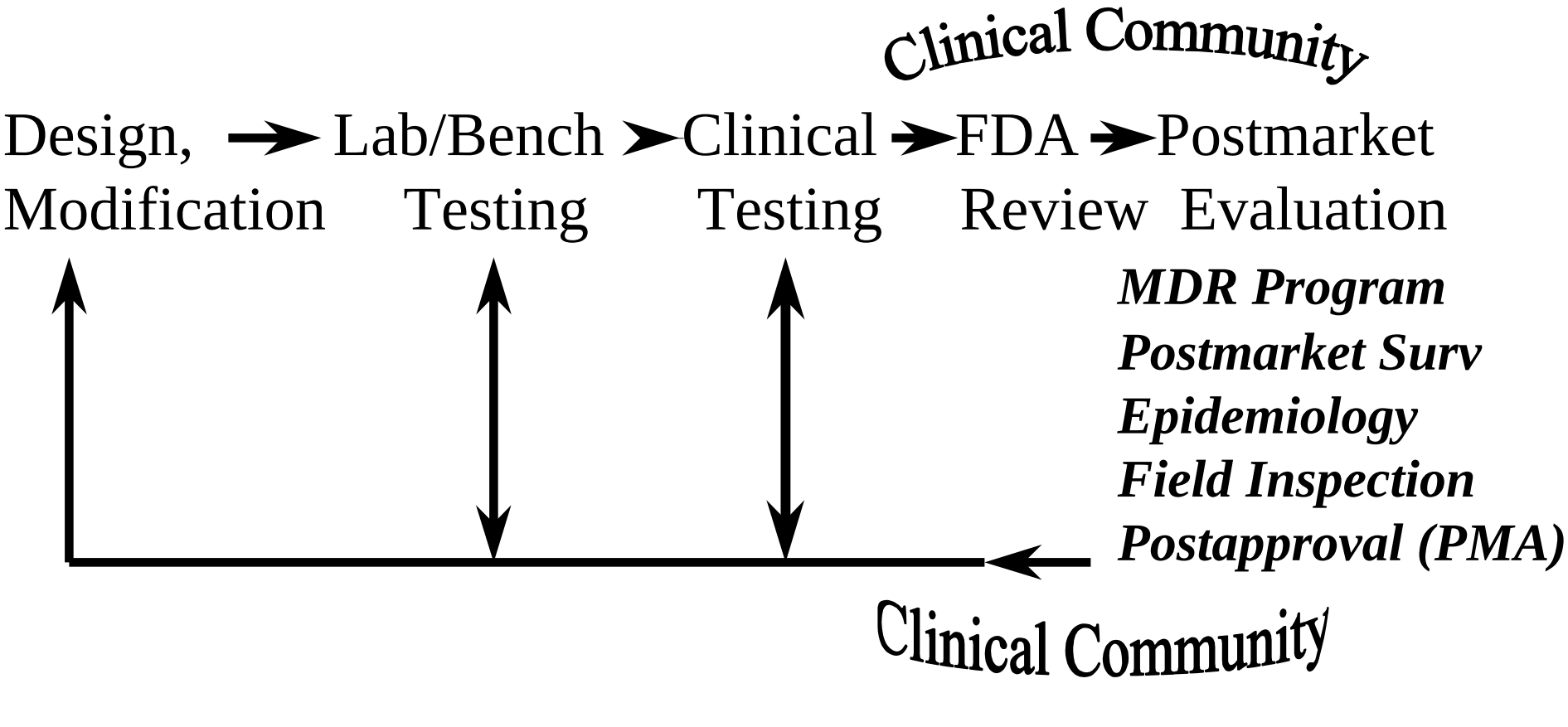
- VERY BRIEF TALK
- VERY BRIEF CONTEXT
- ILLUSTRATION OF MECHANISMS FOR MONITORING DEVICES
- SOLICIT COLLABORATION OF CLINICAL COMMUNITY

From Design to Obsolescence: Medical Devices and Center for Devices and Radiological Health, FDA



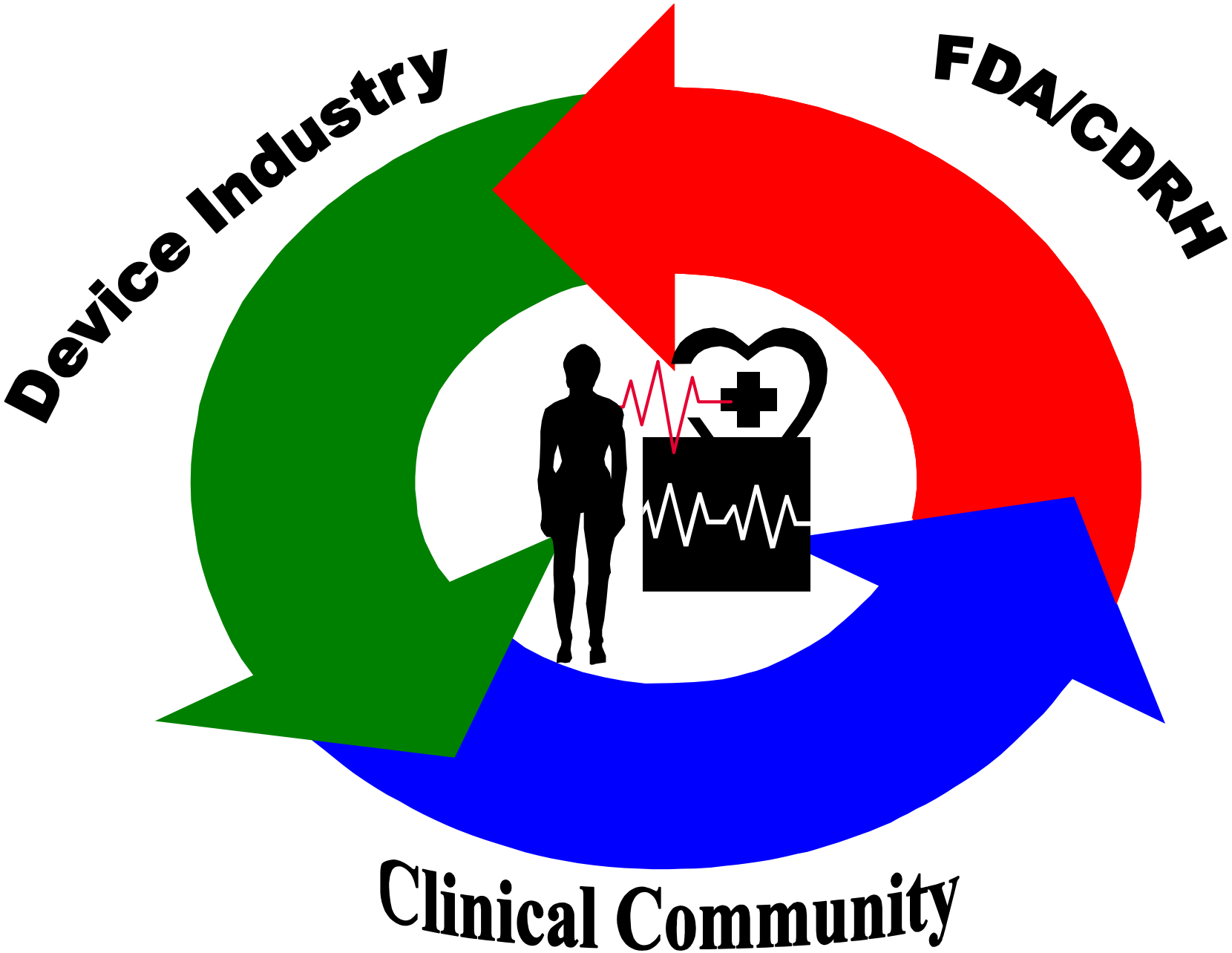
'Design' ⟶ Device evolution ⟶ 'Obsolescence'

Examples of Device Monitoring

- Medical Device Reporting System: industry and health professionals report spontaneous adverse events
- Epidemiology studies by FDA
- FDA review of literature: non-FDA studies of medical device use and problems
- Medical Device Surveillance Network: new program for user facility reporting

Examples of Device Monitoring

- **Medical Device Reporting (MDR) System: NIR on Ranger with Sox**
- **Epidemiology: Stent failure rates: Comparison between men and women**
- **FDA Review of Literature: Minute Ventilation Pacing; Pulmonary Artery Catheterization and Clinical Outcomes (PACCO)**


Device Industry
FDA/CDRH
Clinical Community